DEPARTMENT OF HEALTH & HUMAN SERVICES

9/7/7d

Food and Drug Administration

Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

September 7, 2001

Ref: 2001-DAL-WL-35

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Alfredo E. Zorzi, Jr.
President and Owner
Hallmark Sales Corporation
1601 Peachleaf Street
Houston, Texas 77039

Dear Mr. Zorzi:

During an inspection of your firm located in Houston, Texas on August 7 and 9, 2001, our investigator determined that your firm repacks first aid kits and sterile surgical kits. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. Significant GMP deviations include, but are not limited to, the following:

1. Failure to establish management review procedures and failure to document the dates and results of management reviews [21 CFR 820.20(c)]. For example, your firm has reportedly held management meetings to discuss product quality but has not kept documentation of such meetings [FDA-483 Items 13 and 14].

2. Failure to document the dates and results of quality audits [21 CFR 820.22]. For example, your firm has reportedly conducted quality audits but has not kept documentation of such audits [FDA-483 Items 16 and 19].

3. Failure to maintain device master records [21 CFR 820.181]. For example, the device master record for each type of the device kits does not include or refer to the location of all device specifications, production and process specifications, packaging and labeling specifications, and quality assurance procedures [FDA-483 Item 5].

4. Failure to maintain device history records for each batch, lot, or unit to demonstrate that the devices are manufactured in accordance with the device master records [21 CFR 820.184]. For example, your firm's Quality Control Standard Operating Procedure (SOP) does not define what information shall be included in the device history records [FDA-83 Item 7].

5. Failure to establish and maintain procedures for acceptance activities [21 CFR 820.80]. For example, your firm:

   (a) has not established acceptance procedures for acceptance or rejection of finished device production runs, lots or batches [FDA-483 Item 3].

   (b) has not established incoming acceptance criteria for the EO gas cartridges, humidichips, sterilization bags, biological indicators, EO dosimeters, and poly-paper surgical kit packaging [FDA-483 Item 11].

6. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers [21 CFR 820.50]. For example, your firm has not specified quality requirements for suppliers, maintained lists of approved suppliers, and developed written procedures describing how suppliers are evaluated for quality acceptance requirements [FDA-483 Items 21 and 22].

7. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100]. For example, your firm has not developed procedures addressing how quality sources are identified and evaluated for corrective and preventive actions [FDA-483 Item 10].

8. Failure to validate the EOGas Sterilization Process (bag sterilization of the surgical trays/kits) and the package sealing process with a high degree of assurance [21 CFR 820.75]. For example, your firm has not defined, tested, and documented EO cycle parameters, humidity, product load configurations, product bioburden, EO residuals and effects on the product, package sealing parameters, and product sterility expiration date in order to achieve a sterility assurance level of 10^{-6} [FDA-483 Items 4 and 8].

9. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications [21 CFR 820.70]. For example, your firm:

   (a) has not documented any monitoring processes for the kit assembly operations [FDA-483 Item 1].

   (b) has not performed routine monitoring of the environmental controlled room for product bioburden, room temperature, and room humidity [FDA-483 Item 1].

   (c) has not established procedures describing how your firm monitors the sterilization temperature inside the EOGas System [FDA-483 Item 2]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued (a copy of FDA-483 is enclosed) at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

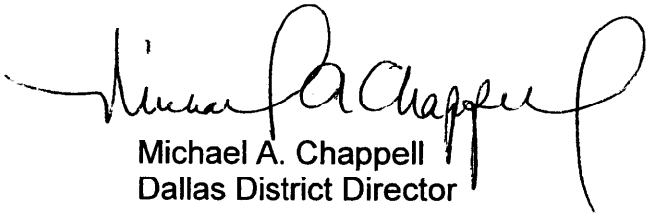
You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Mr. Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

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Enclosure